REMARKS

Applicant has carefully reviewed the Office Action dated Oct. 23, 2006. Claims 29-30, 33-34, 36-40, and 50-51 have been amended in the present response. Claims 52-88 are newly added, including new independent claims 52, 64, 74, 84, 87, and 88. The original claims in the present application were earlier restricted into 4 groups, totaling 10 species. Applicant respectfully submits that the newly added claims fall with the initial restriction requirement, as all the newly added claims fall within the tri-leaflet grouping and species.

Applicant has electronically filed a petition for extension of time and a supplemental IDS, containing results of a PCT International Search Report and a foreign reference cited in that ISR.

Applicant respectfully requests entry of the amendments, reconsideration, and withdrawal of the claim rejections.

The International Search Report

Applicant has briefly discussed the X and Y references for the Examiner's convenience. The Examiner is of course encouraged to read the ISR each of the references in order to provide a thorough Examination.

Wright et al. (U.S. 3,932,898) discuss a pyrolytic carbon coating (column 2, lines12-13).

Mhatre et al. (U.S. 5,326,372) discuss various valves having recesses 29, 59, and 89, listed in a table at column 15, lines 12-54. These recesses are referenced in FIGS 1, 1B4, 4A, 4B, 5, 5B, 8, 8A, 8B, 9, 9B, 12, 12A, 12B, and 12C. Mhatre does not teach or suggest these recesses providing a through-hole. Mhatre et al. teach avoiding blood stagnation and clotting through ear members and adjacent edges wiping the surfaces (Abstract). Mhatre et al. do discuss holes 32, 62, and 92, listed in the table in column 15. For example, ring member 20 includes holes 32, having a bearing housings 28 mounted and seated in hole 32, providing a fluid tight joint (column 9, lines 45-55). Mhatre et al. also discuss pyrolytic carbon coatings. Mhatre et al. do not disclose or suggest the presently claimed invention.

US 6,039,750 (Carpentier et al.) and US 2001/0025197 (Shu et al.) have already been considered by the Examiner.

The 35 U.S.C. §103(a) Rejection

Claims 29-40 and 50-51, all dependent from claim 29, were rejected under 35 USC 103(a) as being unpatentable over Carpentier et al. (US 6,039,759) further in view of either Hanson et al (US 4,276,658) or Bokros (US 4,178,639).

Claim 29, as amended, recites:

"A tri-leaflet prosthetic valve comprising an annular valve body having an inner surface ... and three substantially identical leaflets mounted in said annular valve body ... , said annular body having three pairs of symmetrically placed hinges extended from said annular body for pivotally supporting said leaflets, each of said hinges having ... an opening extending into the valve body;

and each of said leaflets having opposed ears ...

with said ears pivotally received in said hinge openings, wherein each of said openings include a hole extending entirely through the valve body.

Examples of some hinge opening embodiments having a hole extending entirely through the valve body may be seen in the present application near reference numeral 327 in FIG 3B, and un-numbered in FIGS 3G and 3H. Other examples may be found at 441 in FIGS 4A and 4B; at 430 in FIG 4d; and at 445 in FIG 4E. Still others may be seen in FIGS 4h, 4i, and 4k. Examples may also be found in FIGS 4n and 4p. FIG 4p illustrates a hinge opening in the shape of a symmetrical butterfly having a flat bottom and being about half open, where the opening extending through the valve body covers only about the upper half of the opening bottom. FIGS 5A and 5B illustrate a tri-leaflet valve having hinge openings in the valve body having an opening extending through the valve body. FIGS 5e-5h, and 5i-5l also illustrate this recited feature. Other FIGS may also illustrate the hinge openings from other viewpoints. The figures

just named are examples of some embodiments of the present invention, and are intended to illustrate, not limit the scope of the invention, recited in the claims.

Carpentier et al., U.S. patent U.S. 6,039,759 (hereinafter Carpentier) discuss butterfly shaped recesses 22 and 24 which receive leaflets 26 and 28 (col. 6, lines 49-53; FIGS 1-3a). There is no disclosure or suggestion that the recesses have holes extending through the valve body. Carpentier also discuss butterfly shaped recesses 522 and 524 in the spaced apart surfaces in projections 514' which receive valve leaflet projection 530 and 532 (column 13, lines 7-32; FIGS 21-23). Carpentier also discuss recesses 422 and 424 which receive leaflets 426 and 428 (column 12, lines 39-47; FIGS 17-20). Again, there is no teaching or suggestion of the recesses having through holes.

Hanson et al. (U.S. 4,276,658) discuss retaining means having bearing surface 28 (column 2, lines 62-68). Hanson also discusses leaflet ears 31 engaging bearing surface 28 (column 3, lines 29-36; FIG 5). Hanson states that the use of prior art hinge pins received in a recess in the body result in "an area of potential blood stagnation with potential clotting consequences. " Hanson states that his design uses "ears 31 to sweep through the recesses of the retaining means 21 to wipe or flush them out and eliminate, or at least greatly reduce the stagnation problems...." (column 4, lines 59-68). Hanson does not teach or suggest allowing blood to flow through the recesses through the valve body.

Bokros (U.S. 4,178,639) states that supports 21 contain a pair of spherical depressions 41, in which the leaflet ears 27 are received in depressions 41 (column 3, lines 22-28; FIGS 4 and 5). Bokros does not teach or suggest hinge openings extending through the valve body.

Applicant respectfully submits that the hinge design of the tri-leaflet valve in the instant application is different from the cited references. The recited hinge structure allows a better wash of the hinge area (from the inside to the outside of the housing) during opening and closing of the valve. It may provide a complete wash by the flow passing the valve, even when the valve is closed in some embodiments. Applicant believes this washing provided by the hole through the valve body may significantly reduce the likelihood of blood clots forming in the hinge opening area, relative to an opening which is a blind cavity not allowing fluid flow through the valve body through the opening. Applicant further believes that thrombosis may begin in the

hinge area and grow from the hinge area to cover the leaflets, causing valve failure, in many prior art designs.

Applicant respectfully submits that neither Carpentier, Bokros, nor Hanson, either alone or in combination, teach or suggest the hinge opening structure recited in claim 29 and the claims dependent therefrom. Newly added independent claims 52 and 84, and claims 53-64 and 85-86 dependent therefrom, also recite this novel hinge opening structure. Applicant respectfully requests allowance of claims 29, 52, and 84, and the claims dependent therefrom.

Claims 35, 36, and 51 were rejected under 35 U.S.C. 103(a) as unpatentable over Carpentier et al. (US 6,039,759) further in view of either of Hanson et al (US 4,276,658) or Bokros (US 4,178,639), and further in view of Bokros (U.S. 3,685,059). This rejection was related to "nanosized carbon particles". Claims 35, 36, and 51 are dependent from claim 29, and for the reasons stated above, are patentable over these references.

The Composite Material and Surface Material Limitations

Claim 35 recites "The tri-leaflet prosthetic valve as in claim 29, wherein the valve body and the leaflets are further coated with nanostructure engineered carbon." The materials of construction limitations of claim 35-37, claim 51, and other newly added claims are discussed immediately below, beginning with claim 64.

Newly added claim 64 recites:

A tri-leaflet prosthetic valve comprising:

an annular valve body disposed around a central axis, the valve body having a passageway therethrough;

three leaflets pivotally coupled to said annular valve body and configured to translate between a closed position impeding blood flow through the valve body passageway and an open position allowing blood flow through the passageway;

in which the valve body includes a composite including pyrolytic carbon and carbon nanofibers.

Claim 64 thus recites a composite, where the composite includes pyrolytic carbon and carbon nanofibers. As applicant discusses below, none of the cited references teaches or suggests a valve body (or leaflets) including such a composite.

Applicant summarized some embodiment processes in the Summary on page 3 (Paragraph 18 in the Patent Application Publication). The Summary discusses "the integration of the pyrolytic carbon (PyC) deposition and catalytic vapor grown carbon fiber (VGCF) growth into a single operation." While the structural claims currently under consideration are not limited by the processes used (the processes are recited in other, currently withdrawn claims), reading the process discussion may aid in understanding the composite materials formed by the Applicant.

Carpentier et al. (US 6,039,759) do not discuss any such materials of construction. Hanson discusses a graphite substrate having a pyrolytic carbon coating (column 4, lines 28-35). Hanson does not even teach or suggest a composite, and does not teach a composite including pyrolytic carbon and carbon nanofibers. Borkos '639 discusses the components being "made from isotropic graphite ... which has been suitably coated with pyrolytic carbon." (Column 2, lines 43-52). Bokros '639 does not teach or suggest a composite including pyrolytic carbon and carbon nanofibers.

Bokros et al., U.S. 3,685,059 (hereinafter Bokros '059) discuss various pyrolytic carbon coatings for prosthetic valves. Bokros '059 states that anistropic carbons, though thrombo-resistant, tend to delaminate when complex shapes are cooled after coating at high temperatures (column 2, lines 32-39). Bokros suggests using pyrolytic carbon having a BAF of not more then 1.3 (where a BAF of 1.0 is perfectly isotropic) for complex shapes. Bokros '059 then discusses that a BAF of 2.0 can be used for non-complex shapes, and even 20 for flat shapes. See column 2, lines 40-53. Bokros states that "For use on complex shapes and in order to obtain maximum strength, it is desirable that the pyrolytic carbon be nearly isotropic (column 2, lines 32-34). Bokros '059 claims a prosthetic device having an isotropic pyrolytic coating (Claim 1). (All emphasis added.)

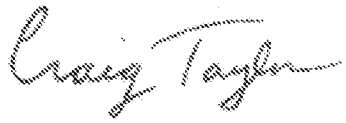
Bokros et al., U.S. 3,685,059 (Bokros '059) do discuss a pyrolytic carbon coating having silicon carbide additive. See Column 13, lines 10-17, and other locations. The resulting SiC is

very thrombogenic. Bokros '059 suggests that the particles should be isotropic pyrolytic carbon (i.e. orientated randomly, similar to prior art FIG 10a in the present application). In contrast, FIG 10b illustrates one embodiment of the present invention in a pyrolytic carbon surface layer coating. FIG 10b illustrates the graphite domains being preferred aligned so the surface consists of the graphitic basal planes, so that surface of the final device can have parallel aligned graphite planes. This is an orientation of the pyrolytic carbon surface to reduce interaction between the material and its biologic environment. Bokros '059 does not teach or suggest coating a heart valve with pyrolytic carbon having parallel aligned graphite planes. Bokros '059 nowhere even discusses a composite material including pyrolytic carbon and carbon nanofibers. Accordingly, Applicant submits that dependent claims 30-35-37, 51, and newly added independent claims 64,74, 87 and 88 (and the claims dependent there from) are allowable over the reference of Carpentier, Hanson and Bokros.

The improved, open hinge structures recited may provide improved washing of the hinge structure and reduced thrombosis caused valve failure. The valve body and/or leaflet construction recited including a composite material including pyrolytic carbon and carbon nanofibers may provide improved mechanical properties over some currently used more brittle materials. The improved surface structures recited may provide prosthetic heart valves requiring lower amounts of blood thinning agents. Applicant respectfully submits that the prior art discussed in the Office Actions do not teach any of these aspects of the present invention.

Issuance of all pending claims is respectfully requested. If a telephone conference would be of assistance, please do not hesitate to contact the undersigned attorney, at 651.707.3595.

Sincerely,



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